FEB 2 2 2001

Revised

VI. Safety and Effectiveness Summary

K003914

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number:	2021898
Address of Manufacturer:	Medtronic PS Medical 125 Cremona Drive Goleta CA, 93117 (805) 968-1546 ext. 1776 Fax: (805) 968-5617
Contact Person:	Janet McAuley
Date:	December 20, 2000
Trade or Proprietary Name:	Medtronic PS Medical NeuroPEN Endoscope and Optical Accessories
Common usual or Classification Name:	Neurological Endoscope (882.1480)
Predicate Device Identification:	Clarus NeuroPEN Endoscope (K942249, K926048)

Description: The Medtronic PS Medical, NeuroPEN Endoscope is a flexible tubular device with a thermo-formed plastic proximal handle.

Intended Use: The Medtronic PS Medical NeuroPEN Endoscope is intended for accessing and visualizing nerves, neural tissue, and surrounding tissue where cerebrospinal fluid may be contacted during neurosurgery, including intracranial procedures. These procedures may include Shunt placement, 3rd Ventriculostomy, and visualization for diagnostic procedures such as Loculated hydrocephalus. The endoscope is passively deflectable and has an irrigation channel for sterile fluid flush.

The High Resolution Optical Coupler is designed for use with all Medtronic PS Medical endoscopes. The Coupler is used to connect the endoscope to the camera head, and magnifies the image of Medtronic PS Medical endoscopes.

The Expansion Ring is indicated for use with all Medtronic PS Medical endoscopes with the exception of the Medtronic PS Medical 30K High resolution Neuroendoscope. The Expansion ring converts the optical magnification to a larger image on the video monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Ms. Janet McAuley
Regulatory Specialist
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117

Re: K003914
Trade Name: Medtronic PS Medical NeuroPEN Endoscope and Optical Accessories
Regulatory Class: II
Product Code: GWG
Dated: December 15, 2000
Received: December 19, 2000

Dear Ms. McAuley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Revised Indications for Use Statement

Device Name: NeuroPEN Endoscope and Optical Accessories

Abbreviated 510(k) Number (if known): K003914

Indications for Use:

The Medtronic PS Medical NeuroPEN Endoscope is intended for accessing and visualizing nerves, neural tissue, and surrounding tissue where cerebrospinal fluid may be contacted during neurosurgery, including intracranial procedures. These procedures may include Shunt placement, 3rd Ventriculostomy, and visualization for diagnostic procedures such as Loculated hydrocephalus. The endoscope is passively deflectable and has an irrigation channel for sterile fluid flush

The High Resolution Optical Coupler is designed for use with all Medtronic PS Medical endoscopes. The Coupler is used to connect the endoscope to the camera head, and magnifies the image of Medtronic PS Medical endoscopes.

The Expansion Ring is indicated for use with all Medtronic PS Medical endoscopes with the exception of the Medtronic PS Medical 30K High resolution Neuroendoscope. The Expansion ring converts the optical magnification to a larger image on the video monitor.

When attached to the Optical Coupler, the Eyepiece has two distinct uses: the Eyepiece may be used to adapt the Coupler to a B-mount video camera; the Eyepiece may also be used for direct-to-eye viewing using a Medtronic PS Medical endoscope.

The C to V adapter is used to adapt the Optical Coupler for use with a V mount video camera.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: ✓
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003914

(optional format 1-2-96)